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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,731	09/25/2003	Samuel Scheinberg	DBH: 0293.0028	9423
152	7590	08/25/2005	EXAMINER	
CHERNOFF, VILHAUER, MCCLUNG & STENZEL 1600 ODS TOWER 601 SW SECOND AVENUE PORTLAND, OR 97204-3157			LEWIS, KIM M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/672,731	SCHEINBERG ET AL.
Examiner	Art Unit	
Kim M. Lewis	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 27 January 2005.

2a)  This action is FINAL.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-44 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) 31-39 is/are allowed.  
6)  Claim(s) 1-14, 17-23, 25-30, 40-42 is/are rejected.  
7)  Claim(s) 15, 16, 24, 43 and 44 is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: *Detailed Action*.

## **DETAILED ACTION**

### ***Summary***

1. The Office action mailed on April 19, 2005 was incomplete in that claims 2, 5-7, 21 and 41 were not properly rejected, objected to or indicated allowable. Thus, this complete Office action replaces the Office action mailed April 19, 2005.

### ***Response to Amendment***

2. The amendment filed on 1/27/05 has been received and made of record in the application file wrapper. As requested claims 26 and 28 have been amended and 40-44 have been added.

3. Claims 1-44 are currently pending in the instant application.

### ***Claim Objections***

4. Claims 6 and 7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. More specifically claim 6 depends upon itself and therefor fails to further limit the subject matter of previous claim.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 6 and 7, the metes and bounds of the claims cannot be determined and are therefore indefinite. Applicant is required to amend the dependency of claim 6. Since the metes and bounds cannot be determined, the examiner will reserve prior art rejections until the dependency of claim 6 has been amended.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

8. Claims 1, 2, 4, 8, 9, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,320,093 ("Augustine et al.").

As regards claims 1 and 2, Augustine et al. discloses a bandage for autolytic wound debridement, which anticipates applicant's claimed invention. More specifically, Augustine et al. disclose in Figs. 3 ad 3A, a bandage, which protects the wound of a user, comprising a skin contact layer (316) of a flexible film having opposite first and second sides, a hollow dome (315) of flexible film attached to and extending over a

portion of said first side of said skin contact layer (col.7, line 64- col. 8, line 18). As can be seen from Figs. 3 and 3A, said hollow dome has a height and a top portion, the top portion being freely movable along said first side of said skin contact layer through a distance related to said height and said second side being adhesively attachable to a surface intended to be protected via adhesive (328).

Regarding claim 4, as can be seen from Figs. 3 and 3A, the adhesive is missing from the second side of the skin contact layer opposite and aligned with the dome.

Regarding claim 8, note the skirt portion of the device of Augustine et al. located at surface (321).

As regards claim 9, note the use of adhesive at col. 8, lines 14-18.

As regards claim 10, note the portion extending down from the top portion.

Regarding claims 13 and 14, as can be see from Figs. 3 and 3A, the skin contact layer is elongate and has larger dimensions than the dome top layer and extends beyond the dome top layer in both of a pair of opposite directions.

#### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 3, 11, 12, 17-20, 22, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Augustine et al.

As regards claim 3, Augustine et al. fail to teach the bandage of claim 2, wherein said layer of adhesive material is coextensive with the second side of the skin contacting side. However, it is known in the art to provide bandages with adhesive layers that are coextensive with the layer of the bandage that contacts the skin (usually a second surface of backing layer) in order to seal the bandage to the skin to keep out contaminants. Note for example the bandage described in U.S. Patent No. 5,170,781.

As such, it would have been obvious to one having ordinary skill in the art to provide the bandage of Augustine et al. with an adhesive layer that is coextensive with the second side of the skin contacting side in order to seal the entire surface of the bandage to the skin to keep out contaminants.

As regards claims 11 and 12, Augustine et al. fail to teach the top portion of the dome is flat or an arcuate transition portion interconnecting the sidewall with the top portion. Absent a critical teaching and/or a showing of unexpected results derived from manufacturing the top portion of the dome with a flat top that extends parallel to the skirt an arcuate transition portion interconnecting the side wall with the top portion or the transition portion interconnecting the side wall with the top portion, the examiner contends that the shape of the top portion and the portion an arcuate transition portion interconnecting the side wall with the top portion is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claims 17-20, 22 and 23, Augustine et al. fail to teach that the height of said dome is at least 4 mm, that the bandage has a thickness not greater than 0.153 mm, that the dome top layer is thinner than said skin contact layer, that the skin contact layer is of a material which is more elastic than said dome top layer, that the dome is circular, or that the said skin contact layer is oval.

Absent a critical teaching and/or a showing of unexpected results derived from the height of said dome being at least 4 mm, the bandage having a thickness not the skin contact layer being of a material which is more elastic than said dome top layer, the dome being circular, or the skin contact layer being oval, the examiner contends that

these claimed features are an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claim 21, Augustine et al. disclose at col. 8, lines 3-9 that the cover layer (315) is "sturdy, yet somewhat flexible". Also, col. 8, lines 44-47 disclose that cover (315) provides a measureable MVTR.

As regards claim 25, Augustine et al. is silent as to a hydrocolloid material covering the second side of the skin contact layer. Instead, Augustine et al. disclose an adhesive. However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute the adhesive disclosed by Augustine et al. for a hydrocolloid adhesive because hydrocolloid adhesives are well known and used for maintaining its adhesiveness while absorbing wound exudate.

13. Claims 26-30 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,170,781 ("Loomis").

As regards claims 26 and 27, Loomis substantially discloses all features of the claimed invention. More specifically, Loomis discloses a bandage comprising: (a) shaping a flexible film to form a flexible dome including a flexible side wall and a top portion (forming the bubble 120B), leaving said dome surrounded by a generally planar skirt of said flexible film extending radially outward from said dome (note the skirt in Fig. 5); and attaching said skirt adhesively to a generally planar skin contact layer of a flexible film that extends at least beneath all of said dome so that said top portion is movable along said skin contact layer (note adhesive 104b and col. 2, lines 53-58).

Loomis fails to teach the order in which portions of the bandage are attached to each other. Absent a critical teaching and/or a showing of unexpected results derived from the order of steps in constructing the bandage, the examiner contends that the steps are not critical and therefore do not patentably distinguish applicant's invention.

As regards claim 28, note layer (148B).

As regards claim 29, note adhesive (104B).

As regards claim 30, Loomis is silent as to perforations. However, it would have been *prima facie* obvious to one having ordinary skill in the art to provide perforation in the bandage, for example, in layer (102B), in order to allow the user's kin to breathe.

Regarding claim 40, note the rejection of claims 26 and 29 above.

#### ***Allowable Subject Matter***

14. Claims 5, 15, 16, 24 and 41-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
15. Claims 31-39 are allowed.

#### ***Response to Arguments***

16. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

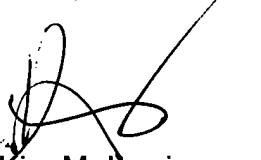
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-

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4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis  
Primary Examiner  
Art Unit 3743

kml  
August 22, 2005